Response to Claim Rejections under 35 USC § 112

Page 2, of Office Action dated 02/26/03:

It is well known in the field of dry chemistry that the secret or the whole basis of the dry chemistry technology and the why how of the reactions occurring on the strip(s) are all based on the fact that the strips are kept dry because the reactants will react once the strip(s) are exposed to liquid (e.g. urine, etc.). In fact, during manufacturing the moisture in the dry rooms is kept well below 30% to avoid the reaction taking place prior to packaging the strip(s) in air-tight container(s) with dessicant. As stated clearly in the specification, the HIV antibody (if present) will bind to the HIV antigen and enzyme conjugate. Immediately causing less reaction to occur (color develop) due to the neutralization of the enzyme. No enzyme activity, no reaction / color development. If there is no HIV antibody present in the sample, then the reaction will go to completion with no competition from the antibody and full color development will occur. This response should completely alleviate any rejection to claim 23 and 27 and the effects that they have on claims 24-26, 28 and 29. It is not understood of any other position with regards to these claims is legally defensible? The applicant has requested assistance with the claim drafting under MPEP 707.07(j) and Examiner has provided some assistance and applicant has repeatedly complied with the Examiners helpful suggestions. Why the continued rejection?

Page 3, of Office Action dated 02/26/03:

The claim rejection based in "new matter" in the claims. The applicant has only limited the claims further? How can this be presented as "new matter" and require further consideration? If this response does not result in a favorable response from the Examiner the applicant will file an RCE under 37 CFR 1.114. It would appear to be much quicker if the Examiner provided additional assistance with the MPEP 707.07(j) request so the prosecution of this application could be accelerated to completion.

The applicant has removed the negative limitation "Western Blot and Thin Layer Liquid Phase" but leaves in the limitation "ELISA" in the claims and adds "**HPLC**". See page 19 of the specification 3rd paragraph. It clearly states "this new art **eliminates** the need to

use the prior art methods of detection, specifically **HPLC and ELISA**". This would obviously remove any rejection to the claims 23-29. In fact, this overcomes all of the new rejections based on Weinstein and Schlederer.

Response to Claim Rejections under 35 USC § 102

The newly amended claims have overcome the Examiners rejection of claims 23-29 under 35 U.S.C. 102(b) as being anticipated by Weinstein. This reference describes a method for the detection of HIV in saliva using nitrocellulose. There is no **chromatography** used in this method what so ever. This method clearly describes multiple steps (which are not required by the present art)such as **total immersion** of the whole strip in 5 mL of saliva in tubes (this is a very large amount which makes it unusable in the practical sense and archaic) **not required by the present art (physical distinction)**, fasting samples (impractical) **not required by the present art (physical distinction),** incubation 30 minutes (time consuming) **not required by the present art (physical distinction)**, strips of cellulose are then washed un cool tap water **not required by the present art (physical distinction)**, then incubated for 20 minutes iwht goat antibodies (very, very time consuming) **not required by the present art (physical distinction)**, strips are again washed to remove antibodies (very, very, very time consuming, no difference from the ELISA ,method, this is ELISA with the plate, actually this is Western Blot) **not required by the present art (physical distinction)**, strips are then incubated for 10 minutes with NBT/X phos substrate which is again **not required by the present art (physical distinction)**. This is actually a combination of ELISA and Western Blot but more cumbersome and has no physical and ./ or technical resemblance to the present art in any manner. The applicant further remove limited the claims of the current application by limiting the samples to "urine and blood" in an effort to speed up prosecution. There is no chromatography or lateral flow activity whatsoever and has no connection to the current technology. The present art is light-years ahead of the art of

Weinstein art and demonstrates distinct physical features that clears any § 102 rejections. The Smith patent has no such **limitations** as those required by Weinstein. The device of Weinstein has no physical features of Smith technology which is completely different **(novel)** from that of Weinstein clearing the claims of Smith from any §102 rejections. The present art is patentably distinct and "novel" in structure and functionality over the Weinstein device. Because of this and other reasons the Smith device is not limited to all of the requirements of the Weinstein device.

The Examiner rejection to claims 1 - 3 as being anticipated by Weinstein under 35 U.S.C. § 102 should be reversed because Weinstein does not teach applicant's limitations as claimed. Therefore, Weinstein fails the first step of inquiry with respect to a 35 U.S.C. § 102 rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." This Weinstein reference does not because it fails to disclose the use of a urine and blood and the claim limitations as taught. The Weinstein device requires multiple and different steps and indicators that are not required or taught by Smith nor anticipated by Weinstein.

The device of Smith uses a **"new principle of operation"** in that the use of a single step to detect HIV antibodies using new methods and indicators not taught prior to the present device with the ability to detect the presence of HIV antibodies within 3-5 minutes not hours. The multiple steps of Weinstein are not and should not be required of the present arts technology. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35 U.S.C. 102, and because the invention of Smith recites numerous novel physical features

that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102 should be reversed.

The Claims Rejection Under 35 USC § 103

The claims 23-29 which are currently rejected under 35 U.S.C. § 103(a) as being unpatentable over Weinstein and view of Schlederer have been overcome by the amended claims. The Weinstein device describes the "Western Bloot / ELISA Hybrid" which hours of incubations and steps which has no physical of technical connection to the present art has been described above. The Schlederer device describes an HPLC method which is a limitation of the present claims requiring a chemchemiluminescence technique which has no relative bearing on the current device which requires no sprectrophotometers, incubations for hours, etc. These two methods as mentioned in the specification are antiquated, archaic and have no structural, functional, or method of use resemblance in any form to the current device. The use of this reference is perplexing to the applicant in that the applicant taught these antiquated references in the original specification. The Weinstein reference is even more perplexing, this is a device that has never made it to market and is nothing more than a paper patent. However, this device as claimed, is a complete dip device that require multiple(s) incubations and treatments that have nothing to do with the present art.

The following requirements of the reference (Weinstein-Schlederer) for analysis by HPLC / DIP that includes/mirrors Western Blot & ELISA techniques:

1) The 5 mLs of saliva.
2) Fasting before collection.
3) The use of electricity required by HPLC, spects, and readers.
4) The multiple steps upon steps with incubations and washes, etc.
5) Chemiluminescence.

6) HOURS of technical time.

The present art requirements for analysis:

1) Random urine approximately 3 to 5 drops.

2) About 3 minutes of technical time.

What the present art **does not** require for analysis:

1) No Incubation.

2) No electricity.

3) No transfer of separated proteins.

4) No gel electrophoresis to include cells, wires, power supply, etc.

5) No Western Blot techniques or requirements.

6) No ELISA techniques.

7) No HPLC

8) No spectrophotometer.

9) No microtiter plates, etc.

10) No washes.

11) No chemiluminescence

12) No transfer and permeation of liquid, etc.

Of course, the obvious stands out that the present art is a **marked** advancement over the prior art goes without saying. The savings in time, money, components, etc., alone, are enormous. Because applicant's newly amended claims 23-29 recite novel physical features (over the cited prior art and the novel physical distinctions of claims 23-29 are unobvious under § 103(a) for the following reasons. The present device produces **unexpected results** due to the inherent design and capability differences between the inventions. When the devices are juxtapose the results produced are unexpected. The present device is a single step method for the analysis of HIV antibodies in urine or other fluids effectively allowing **superior** results with reference to time, cost, and accuracy. The present device requires **no pretreatment, no Western Blot, no ELISA, no HPLC,**

no incubations, no washes, no chemiluminescence., as required by the Weinstein-Schlederer devices. Weinstein-Schlederer devices are complicated, multiple step, and tedious methods for the analysis of HIV and are not an advancement in the art as the case with the Smith patent. The limitations of Weinstein-Schlederer as mentioned do not allow for the **unsuggested** and **superior** capability of the present device. Without a showing in the Smith patent that a complicated device with multiple steps for the measurement of HIV antibodies is required (which there is none) then the newly added limited claimed should be allowed. The present device **omits elements** certain, multiple, and critical elements of the Weinstein-Schlederer devices. The present art by not including these elements of the prior art is in fact more capable of producing a result faster and without the use of electricity enables it to be used in Third World countries, etc. Without question the present art's method for the presence of HIV antibodies in urine or other fluids is a **superior** functional device with reference to time, money, and physical requirements. The prior art of Weinstein-Schlederer do not explain any of the present arts novel features nor anticipate any of the novel features of the present art. There is no reference made by Weinstein-Schlederer to the present art. Therefore, the present art could not have been, nor has it been rendered obvious by the prior art of Weinstein-Schlederer. The applicant's invention **solves a different problem** (detection of HIV antibodies in urine using a single step) that the reference cannot, and such a solution to the different problem is recited in the newly added and amended claims.

Thus the applicant submits that their invention clearly recites novel physical subject matter, which distinguishes over any possible combination or use of Weinstein-Schlederer.

The Newly Added Novel Physical features of Claims 23-29 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 103.

Again, reconstruction of an invention using Weinstein-Schlederer to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... ". It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

Applicant's invention of newly added and limited claims 23-29 are not obvious when compared to the prior art of Weinstein-Schlederer because such prior art as a whole does not teach applicant's invention. Rather, some of the prior art teaches various aspects of detection of HIV antigens and antibodies which are in no manner even slightly similar to the present art. Furthermore, no suggestion is made by any of the prior inventors to combine any of these prior art elements to form applicants' device. For these reasons applicant is entitled to allowance of newly added and limited claims 23-29.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. **Under section 103**, teachings of references can be combined only if there is some suggestion or incentive to do so." In re Fritch, 23 USPQ 2d 1780, 1783 (CAFC 1992).

Weinstein-Schlederer, nor any other prior art separate from applicants' disclosure, suggests that these references be combined, much less be combined in the manner proposed. The proposed combination would not be physically possible or operative. The combination of the referenced prior art to produce the present art is not physically or feasibly possible. Even if Weinstein-Schlederer were to be combined in the manner

proposed, the proposed combination would not show all of the novel physical and functional features of newly added limited claims 23-29 because the combination is impossible and impractical.

"In order to establish a ***prima facie*** case of the obviousness, it is necessary for the examiner to present ***evidence***, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art ***would have been led*** to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can ***reconstruct*** and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a ***prima facie*** case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the ***motivating force*** which would impel one skilled in the art to do what the ***applicant has done.***"

In the present case, there is no reason to support the proposed combination of Weinstein-Schlederer. However the fact that both references teach a device that is supposed to be used in the detection of HIV is not sufficient to **gratuitously and selectively** substitute parts of one reference for a part of another references in order to attempt to meet applicants' novel claimed invention.

Even if the Prior Art References Were To Be Combined In The Manner Proposed, The Proposed Combination Would Not Show All Of The Novel Physical and Functional Features Of The Claims

Conclusion

For all of the above reasons, applicant submits that the specification and newly added and limited claims are now in proper form, and that the claims all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,

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